Supreme Court, U.S.
FILED
NOV 12 2002
CLERK

No. 02-606

IN THE

Supreme Court of the United States

GE MEDICAL SYSTEMS INFORMATION TECHNOLOGIES, INC.,
Petitioner,

v.

BIOMEDICAL SYSTEMS CORPORATION,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

REPLY BRIEF OF PETITIONER

BRACKETT B. DENNISTON, III
KATHERINE OBERLIES O'LEARY
GENERAL ELECTRIC COMPANY
3135 Easton Turnpike
Fairfield, CT 06431
(203) 373-2453

CARTER G. PHILLIPS
JOSEPH R. GUERRA*
DEREK E. BROWN
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Counsel for Petitioner

November 12, 2002 * Counsel of Record

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20001

18 pp

TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
REPLY BRIEF OF PETITIONER	1
CONCLUSION	10

TABLE OF AUTHORITIES

CASES — Page

Bowen v. *American Hosp. Ass'n*, 476 U.S. 610 (1986) 9

Buckman Co. v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) 3

Norfolk & W. Ry. v. *Ayers*, No. 02-963 (U.S. granted Apr. 1, 2002) 10

In re Orthopedic Bone Screw Prods. Liab. Litig., 159 F.3d 817 (3d Cir. 1998), *rev'd on other grounds*, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) 3

United States v. *Barile*, 286 F.3d 749 (4th Cir. 2002) 9

STATUTE AND REGULATIONS

21 U.S.C. § 396 7

21 C.F.R. § 20.1 6

21 C.F.R. § 801.4 5

Obstetrical and Gynecological Devices; Reclassification of Home Uterine Activity Monitor, 64 Fed. Reg. 41,435 (July 30, 1999) 8

REPLY BRIEF OF PETITIONER

As respondent's opposition unwittingly confirms, this case squarely poses the question whether a manufacturer can submit a 510(k) notification that claims an intended use for a medical device that the manufacturer has no intention of promoting, and for which no physician will ever prescribe the device. Indeed, respondent spends most of its brief arguing that federal law permits the filing of such a pretextual 510(k) notification, that the contrary views of the Third Circuit and the Food and Drug Administration ("FDA") are "dicta" or "mistaken," and that such a deceptive notification poses no health or safety concerns. As GE demonstrates below, respondent's arguments serve only to underscore that the petition raises an important question of federal law that warrants plenary consideration by this Court. The "cryptic" nature of the Eighth Circuit's opinion provides no justification for declining to review a deeply flawed *holding* that conflicts with the ruling of a sister circuit, and with the views of an agency, on a question of federal law crucial to the public health and safety.

1. Although respondent suggests that this case involves questions of state law, its entire argument is that GE would not have violated *federal law* by filing a 510(k) notification for term use as long as GE limited its labeling and promotional efforts to use of the monitor by women whose pregnancies have already reached full term. In making this claim, moreover, respondent expressly concedes or fails to contest these essential facts: (1) Its prior HUAM "was *regularly prescribed for pre-term* . . . use by obstetricians around the country." Br. at 18 (emphasis added). (2) The marketplace is "rife with . . . HUAMs being used by physicians for pre-term" use. *Id.* at 19. (3) The *only* use for its new HUAM identified in the complaint was pre-term monitoring. (4) Every penny in damages that respondent sought – and that the jury awarded – was for pre-term use. (5) Respondent's own medical expert testified that he had

never used a HUAM for term use, and instead "*regularly uses* HUAMs for detection and treatment of *pre-term* contractions." *Id.* at 17 (emphases added). (6) GE's expert testified that he could not imagine why anyone would ever prescribe a HUAM for term use. (7) Respondent offered no evidence that any physician ever prescribes HUAMs for term use.[1]

These uncontested facts thus give rise to a fundamentally important question of federal law that directly affects the ability of the FDA to protect the public health and safety: can a manufacturer lawfully file a 510(k) notification for a particular intended use, with "labeling disclaiming approval for" another use, Br. at 20, even though it knows that the *only* market for the device is for the *unlabeled* use, and that no physician would ever prescribe it for its labeled use. There is nothing "hypothetical" about this legal question, *id.* at 1, which is why respondent devotes so much of its opposition to defending the lower court's resolution of the question. That effort is not only unavailing, it illustrates the conflict the decision below creates with the holding of a sister circuit and with the FDA's authoritative construction of its own regulations and the laws it enforces.

2. In an attempt to show that a 510(k) can lawfully claim an "intended use" for which no physician will ever prescribe the device, respondent argues here, as it did below, that the "intended use" is only "the use for which the applicant is *seeking clearance*," and thus must be determined only "*from the face of the request for 510(k) clearance*, not from [the FDA] regulations cited by GE (Pet. 6) or any other source." Br. at 12-13 (emphases added). This legal contention – which

---

[1] The fact that 10% of the *pre-term* patients for whom HUAMs are prescribed continue to wear them after they reach term, Br. at 22, 27, is not evidence that the device is *intended* for term use, anymore than casts, which are not removed until after broken bones heal, are prescribed or "intended" for use on unbroken bones.

is the basis of the Eighth Circuit's holding below – has been rejected by both the Third Circuit and the FDA.

a. In *In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998), *rev'd on other grounds*, *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the manufacturer argued, like respondent here, that "a statement of intended use is not a representation of fact or intent but, rather, a request for authority" – *i.e.*, a request for "clearance" – that enables the FDA "to limit the authority granted to that which is sought and considered by the agency." *Id.* at 827. In other words, the manufacturer argued that "intended use" is simply the use for which the applicant *seeks clearance*. The Third Circuit flatly rejected this claim, stating that, "[t]o the extent [the manufacturer's] argument is an assertion of law, we find no basis for it in the statute, in the regulations, or in any of the authorities cited." *Id.* at 828.

Confronted with a square circuit conflict, respondent argues that the Third Circuit's disposition of the manufacturer's "intended use" claim was simultaneously "dicta" and a "central" aspect of the decision that this Court overruled. Br. at 24. Both assertions are incorrect. The Third Circuit's resolution of the "intended use" argument was indisputably an essential holding of the case. The manufacturer argued that, because a statement of "intended use" is merely a request for clearance authority (and not an expression of marketing intentions), such a statement cannot mislead the FDA, and thus cannot give rise to any state law fraud claims, even if the manufacturer knows the device will only be used for a different purpose. See 159 F.3d at 826. Resolution of this issue was thus a necessary predicate to the court's preemption holding. Unless the intended use statement could have served as a basis for a state law claim of fraud, there would have been no state law claims to preempt.

It is likewise clear that this Court did not overturn the Third Circuit's predicate holding concerning "intended use." Had

this Court done so, it, too, would have had no reason to reach the preemption question. In fact, the central premise of the Court's preemption analysis was that fraud had occurred, but that it was the FDA's job "to police" it. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). Thus, the Third Circuit's holding that a statement of intended use is not merely a representation of the clearance authority a manufacturer seeks, but also a statement that must truthfully reflect the manufacturer's actual intent, remains good law, and the decision below plainly conflicts with that holding.

b. The FDA has also squarely rejected the argument that "intended use" is merely the use for which the applicant is seeking clearance, and must therefore be determined from the face of the request for 510(k) clearance alone. Indeed, the FDA told this Court precisely the opposite in *Buckman*.

Citing the very regulation respondent deems irrelevant to the 510(k) process, the FDA explained that "the 'intended use' of a medical device is defined by the 'objective intent of the persons legally responsible for the labeling.'" Brief of *Amicus* Food and Drug Administration at 14, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768) ("FDA *Amicus* Br.") (quoting 21 C.F.R. § 801.4). The agency identified a number of factors extrinsic to the label that are relevant to determining the manufacturer's "objective intent," including "'the circumstances surrounding the distribution of the article'" and "'knowledge' that a product is 'offered and used for a purpose for which it is neither labeled nor advertised.'" *Id.* Thus, the FDA stated that, when it "seeks from [a 510(k)] applicant a statement of a device's intended use, it is *not* simply asking for the use that will appear on the labeling," and that the contrary contention advanced by Buckman (and now respondent) "misreads . . .

the applicable federal standards." *Id.* at 14-15 (emphasis added).[2]

Importantly, the FDA also explained, contrary to respondent's claim here, that § 360c(i)(1)(E)(i) "does not relieve manufacturers of their obligation . . . to truthfully inform FDA of a device's 'intended use' as that term is defined in FDA's 'intended use' regulation." *Id.* at 15 n.2. The agency noted that, in order to protect against "potentially harmful intended uses," the FDA is authorized to require statements regarding "'a use of the device not identified in the labeling.'" *Id.* at 16 n.2 (quoting § 360c(i)(1)(E)(i)(I)). This authority, the FDA explained, makes no sense unless the FDA can determine intended use from evidence outside the label itself.

It is thus clear that, in the expert judgment of the FDA, GE would have violated federal law by filing a 501(k) notification for term use. GE plainly had "'knowledge'" that the HUAM would be exclusively "'offered and used for a purpose for which it is neither labeled nor advertised.'" *Id.* at 14. Indeed, as respondent itself states, it was "common knowledge" that HUAMs are "regularly prescribed for pre-term ('off-label') use," Br. at 10, 18, and that they are *never* prescribed for term use. Given these facts, it is simply indisputable that a 510(k) notification for term use would not have been "bona fide," and instead would have been "a

---

[2] The FDA's brief thus completely refutes respondent's claim, Br. at 14, that the "intended use" regulation, § 801.4, is unrelated to the 510(k) process. In fact, respondent's contention that § 804.1 "defines 'intended use' only for purposes of '§§ 801.5, 801.119 and 801.122,'" *id.*, is absurd. Section 804.1 states that it defines the phrase "intended uses *or words of similar import in §§ 801.5, 801.119, and 801.122.*" 21 C.F.R. § 801.4 (emphases added). These three identified regulations do not actually use the phrase "intended use." Thus, under respondent's reading, § 801.4 does not define the phrase "intended use" in any of the provisions that actually use that phrase.

pretext calculated to clear the device for distribution for other uses." FDA *Amicus* Br. at 15.

Respondent's facile observation that the facts of this case are different from those in *Buckman*, Br. at 26, in no way alters this conclusion. The *legal* issue that the FDA addressed in *Buckman* – the obligation to disclose the actual, bona fide intended use for a device in a 510(k) notification – is identical to the *legal* issue in this case. There is nothing "hypothetical," *id.*, about the Eighth Circuit's ruling that GE would not have "violate[d] federal law" by filing a 510(k) notification that disclosed an intended use for which no doctor would prescribe the device. App. 2a-3a. And in rendering this judgment, the lower court necessarily did interpret the FDA's regulations, cf. Br. at 26: it rejected GE's arguments, based on the FDA *Amicus* Brief, that a 510(k) notification for term use would have been an unlawful pretext under the agency's regulations.

Finally, it is fanciful to suggest that the FDA's routine refusal to permit one of its employees to testify as a witness in the proceedings below demonstrates that the legal issue raised by this case is of no concern to the agency. See Br. at 25-26. The FDA denied such permission "[b]ecause of FDA's limited resources and the vast number of requests the agency receives." See Reply App. 2a; see also 21 C.F.R. § 20.1. Nowhere did it state that the proper interpretation of its "intended use" regulation and the statutes governing the 510(k) process were unimportant. Should the Court harbor any doubts concerning the importance of these matters to the agency's fulfillment of its mission, the proper course would be to solicit the government's views on the subject.

In short, the Eighth Circuit's interpretation of the 510(k) regulations and statutes is fundamentally inconsistent with the interpretation rendered by the agency charged with administering them, and with the judgment of the Third

Circuit.[3] This Court should grant the petition in order to resolve this conflict over the obligations of a manufacturer seeking 510(k) clearance.[4]

3. Alternatively, respondent attempts to brush aside the FDA's expert views as an impermissible effort by the agency to "expand[] its jurisdiction," Br. at 26, and "become a policeman against off-label use" *Id.* at 20. These arguments confirm that, contrary to respondent's claims, the decision below involves very significant health and safety issues that underscore the necessity of this Court's review.

Throughout its opposition, respondent repeatedly asserts that, "[f]rom a medical standpoint," a HUAM is "use[d]" in precisely the same manner for pre-term and term patients, *id.* at 4; see also *id.* at 2, 15; that the device poses no safety threat to a pre-term woman, *id.* at 2, 10; and that pre-term monitoring is a common form of off-label use for the many monitors that were cleared for term use only. *Id.* at 17-19. These assertions fly in the teeth of the contrary views of the FDA itself. As GE has explained, between 1980 and 1992, the FDA cleared a number of HUAMs for term use. See at Pet. 8-9. Although the FDA lacks authority to regulate off-label prescriptions of medical devices once the devices are cleared, 21 U.S.C. § 396, it can and does keep abreast of the

---

[3] Contrary to respondent's claim, Br. at 21, GE's bundled reclassification petition and 510(k) notification were not "illegal" under the view of the law adopted by the FDA and Third Circuit. GE sought reclassification for a HUAM intended for use on pre-term patients who had previously experienced a pre-term delivery. This is indisputably a bona fide use for which physicians will actually prescribe the device, not a pretext. GE's filing, moreover, confirms that, properly construed, the contract did not require anyone to "break the law," *id.* at 22-23, and instead required the entirely legal act of filing a bona fide 510(k) notification together with a petition for reclassification.

[4] As the petition itself makes clear, the issue presented concerns the obligations of manufacturers seeking 510(k) clearance, not the applicability of *Auer*, as respondent asserts. Br. at 25-26.

manner in which cleared devices are used. The FDA did precisely this with respect to HUAMs, and found that use of these devices to monitor pre-term patients raised new and unexpected health and safety risks.

While the devices themselves did not directly harm pre-term patients, Br. at 2, 10, the FDA found that they increased the risks of false positives, which in turn often resulted in unnecessary hospitalizations, risky drug treatments, and harmful patient stress. Obstetrics and Gynecology Devices; Reclassification of Home Uterine Activity Monitor, 64 Fed. Reg. 41,435, 41,437 (July 30, 1999). Accordingly, the FDA determined that use of HUAMs for the detection of pre-term labor was a new intended use, and that, for this new use, "the HUAM was not substantially equivalent" to any previously cleared device. *Id.* at 41,436. On the basis of these health and safety findings, the FDA classified HUAMs as Class III devices, and advised manufacturers that it would no longer clear the device for pre-term use unless the device "was reclassified . . . or subject to an approved PMA." *Id.*[5]

This decade-long evolution in the way in which HUAMs were used and in the FDA's clearance policy demonstrates that respondent was not entitled to "the same treatment for [its new] monitor that all competing products had received," Br. at 19, and that the FDA had not already determined that respondent's monitor was safe. Br. at 11. These changes in use and regulatory policy also completely refute respondent's claim that, because other HUAMs had been cleared for term use prior to 1992, the filing of a 510(k) for term use in 1997 would not have violated federal law. Prior to 1992, a statement of intended use for term monitoring would not have

---

[5] Respondent disingenously claims that GE "never uttered a word about safety at trial" and "struggled at trial to suggest that the 'regulatory climate' had changed at FDA." Br. at 9, 19. GE introduced the FDA's Federal Register notice, but was barred from introducing any further evidence about the FDA's health-based change in treatment of HUAMs.

been a pretext designed to evade a clear agency policy of not granting 510(k) clearance for pre-term use. As the undisputed facts of this case make clear, by 1997 this was no longer true.

In discharging its crucial "gatekeeping" function, the FDA is empowered to change the classification of devices, and their eligibility for 510(k) treatment, based on new, and riskier, uses to which previously cleared devices are put. Such changes in the regulatory treatment of new devices pose no threat to the practice of medicine or "off-label" prescription practices. However, by ruling that GE could have legally filed a 510(k) application plainly calculated to evade the agency's new policy towards 510(k) clearance of HUAMs, the decision below significantly undermines the FDA's ability to implement such health-based policy changes in regulatory treatment. Respondent's attempt to convert health and safety regulation into a shell game by itself demonstrates the need for review of the ruling below.

4. Finally, respondent argues that this Court should ignore the conflict the decision below creates with another circuit and with the FDA because the opinion is too "cryptic" to serve as a "road map" for future regulatory violations of the type the Eighth Circuit blessed in this case. Br. at 9, 11. This Court, however, "'reviews judgments, not opinions.'" *Bowen* v. *American Hosp. Ass'n*, 476 U.S. 610, 625 n.11 (1986) (quoting *Chevron U.S.A. Inc.* v. *Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842 (1984)). It is the judgment below that conflicts with a holding of the Third Circuit as well as the expert views of the FDA, and this judgment should therefore be reviewed.

Of equal importance, the decision below can and will serve as both a blueprint for filing pretextual 510(k) notifications, and, perhaps even more importantly, as a defense to any persons who file such notifications. As *Buckman* itself makes clear, the filing of pretextual 510(k) notifications is regrettably more "commonplace," Br. at 9, than anyone would wish. See also *United States* v. *Barile*, 286 F.3d 749

(4th Cir. 2002) (reversing conviction for false 510(k) submission). And, as *Buckman* further demonstrates, the filing of such 510(k) submissions can cause serious injury to a great many people. Though devoid of reasoning, the Eighth Circuit's opinion makes clear that it involves the legality of 510(k) notifications. Accordingly, a manufacturer determined to evade meaningful review, or one accused of having filed a pretextual notification, will have no difficulty "familiari[zing] itself with the underlying facts" of this case, Br. at 11, which are a matter of public record. Such a manufacturer, moreover, will undoubtedly rely on the decision below as authority for why its conduct, like that contemplated under respondent's construction of the Transfer Agreement, did not "violate federal law." Pet. App. 3a. Because the decision below does in fact hold that it is not illegal for a manufacturer to claim an intended use that it has no intention of promoting, and for which no doctor will prescribe the device, the ultimate question is why this Court would turn a blind eye to such a disturbing holding. The integrity of the FDA's regulatory process and decisional consistency among the courts of appeals argue strongly in favor of further review. Compare *Norfolk & W. Ry.* v. *Ayers*, No. 01-963 (U.S. granted Apr. 1, 2002).

CONCLUSION

For the reasons stated above, the Court should grant the petition.

Respectfully submitted,

BRACKETT B. DENNISTON, III
KATHERINE OBERLIES O'LEARY
GENERAL ELECTRIC COMPANY
3135 Easton Turnpike
Fairfield, CT 06431
(203) 373-2453

CARTER G. PHILLIPS
JOSEPH R. GUERRA*
DEREK E. BROWN
SIDLEY AUSTIN BROWN & WOOD LLP
1501 K Street, N.W.
Washington, D.C. 20005
(202) 736-8000

Counsel for Petitioner

* Counsel of Record

November 12, 2002

APPENDIX

APPENDIX

DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
Rockville, MD 20857

[Received Mar. 7, 2001]

CERTIFIED MAIL
RETURN RECEIPT

Edward M. Basile, Esquire
King & Spalding
1730 Pennsylvania Avenue N.W.
Washington, D.C. 20006-4706

Re: Biomedical Systems Corp. v. GE Marquette Medical Systems, Inc.

Dear Mr. Basile:

This is in response to your February 20, 2001 letter to the United States Food and Drug Administration (FDA). Your letter requested the testimony of a FDA employee regarding the review process for reclassification petitions and specifically the GEMMS petition.

As your letter recognizes, a request for testimony from a FDA employee is governed by FDA regulation 21 C.F.R. § 20.1. This regulation prohibits FDA employees from testifying with respect to any information acquired in the discharge of his or her official duties except with the express authorization of the Commissioner of FDA or an employee designated by her to act on her behalf. As Director, Division of Compliance Policy, I have been delegated the authority by the Commissioner to review requests made under 21 C.F.R. § 20.1. *See* 21 C.F.R. § 5.20.

Section 20.1 allows FDA to allocate its limited resources in a manner that best effectuates the agency's public health mission. Section 20.1 provides that FDA may grant a request for testimony if it is determined that such testimony: (1) is in

the public interest, and (2) promotes the objectives of the Federal Food, Drug, and Cosmetic Act (FFDCA) and the agency. Both tests must be satisfied. Because of FDA's limited resources and the vast number of requests the agency receives for agency personnel to participate in litigation, it is not in the public interest, and it does not promote the objectives of the FFDCA, for agency personnel to routinely break from their public health mission to provide testimony in private lawsuits. FDA must deny requests that are unlikely to elicit relevant testimony, unduly burdensome, or otherwise inappropriate. Accordingly, the agency must carefully assess requests for testimony made pursuant to section 20.1. After considering your request, FDA has determined that your request is not in the public interest and does not promote the objectives of the FFDCA, and denies your request for testimony.

While FDA is not unsympathetic to these requests, it must decline to authorize its employees to provide testimony in their official capacity absent compelling circumstances. FDA's policy has been established to avoid the impression that FDA or one of its employees, is taking a partisan position in litigation, where, as here, the agency is not a party. FDA best serves the public not by providing witnesses in private litigation and other matters to which the FDA is not a party, but rather by enforcement of the FFDCA and related statutes. The proposed testimony would not promote the objectives of the FFDCA.

Any participation by FDA employees in disputes between private parties would require that agency employees divert a portion of their time and agency resources, away from primary FDA responsibilities. To allow preferential treatment to only one party in disputes to which FDA is not a party would jeopardize the agency's role as an impartial regulatory agency. If the agency appears to take sides in a private dispute, it would raise legitimate concerns as to the agency's

neutrality and send an inappropriate signal that the FDA may harbor bias toward certain interest. For this reason, the agency attempts to minimize the participation of its employees in controversial matters in which the agency is not a party.

In addition, your request does not differ significantly from many other request in which FDA has or has not taken an action with respect to any device, drug, biologic, food or cosmetic. FDA feels that 21 CFR § 860 explains the review process for reclassification petitions and that non-government experts are available to all parties in this proceeding, if necessary, to assist in interpreting the applicable statutes and regulations.

For the reasons stated above, I am unable to make the findings required by 21 C.F.R. § 20.1 and therefore your request for testimony is denied. If you have any questions, please contact Ms. Anne Smith at (301) 827-0422.

Sincerely yours,

/s/ David K. Haggard
DAVID K. HAGGARD
Director,
Divisions of Compliance Policy